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APPLICATION NO.	FII	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/757,017	757,017 01/14/2004		Heinrich Kladders	1/1448	3319	
28501	7590	12/01/2006	•	EXAMINER		
MICHAEL		RIS LHEIM CORPORA	SINGH, JASVEER			
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Please find below and/or attached an Office communication concerning this application or proceeding.

:	Application No.	,	Applicant(s)	
A.	10/757,017	* '	KLADDERS ET AL.	
Office Action Summary	Examiner		Art Unit	
** ***	Jasveer Singh	de .	3772	
The MAILING DATE of this communication app	ears on the cover	sheet with the c	orrespondence addr	ess
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A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COI 36(a). In no event, however will apply and will expire Society cause the application to	MMUNICATION  er, may a reply be tin  IX (6) MONTHS from become ABANDONE	N. nely filed the mailing date of this com D (35 U.S.C. § 133).	
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3) Since this application is in condition for allowar closed in accordance with the practice under E				
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Disposition of Claims		- CONT.		
4)⊠ Claim(s) <u>1-20</u> is/are pending in the application.		, A		
4a) Of the above claim(s) is/are withdraw		tion.		
5) Claim(s) is/are allowed.		¥ .		
6)⊠ Claim(s) <u>1-20</u> is/are rejected.		Y.		
7) Claim(s) is/are objected to.		¥.		
8) Claim(s) are subject to restriction and/or	r election requiren	nent. 🖔		
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Application Papers	•	1 to		
9)⊠ The specification is objected to by the Examine	r.	÷		
10) ☐ The drawing(s) filed on 14 January 2004 is/are:		or b)⊠ objected	I to by the Examiner	-
Applicant may not request that any objection to the				
Replacement drawing sheet(s) including the correct	ion is required if the	drawing(s) is ob	jected to. See 37 CFF	₹ 1.121(d).
11) The oath or declaration is objected to by the Ex				
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Priority under 35 U.S.C. § 119 🤄		<u>.</u>		
12)⊠ Acknowledgment is made of a claim for foreign	priority under 35	U.S.C. § 119(a	)-(d) or (f).	•
a)⊠ All b)□ Some * c)□ None of:		ij.		B
1. Certified copies of the priority document	s have been recei	ved.		Ш
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3. Copies of the certified copies of the prior	rity documents ha	ve been receiv	ed in this National S	tage 🚬
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1) Notice of References Cited (PTO-892)		Interview Summan Paper No(s)/Mail D		СОРҮ
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)		Notice of Informal		~~
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Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :6/3/2005, 7/25/2005 and 1/14/2005.

#### **DETAILED ACTION**

#### **Priority**

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### **Drawings**

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: bore (25). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings (Figures 5-9) are objected to under 37 CFR 1.83(a) because they are unclear. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

#### Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes." etc.

The use of the trademark Respirat ® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claims 8-9, "the/an inner recess", claim 10 "recess remote," and, claim 18, "corresponding surface," lack proper antecedent basis.

#### Content of Specification

- (a) <u>Title of the Invention</u>: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.
- (b) <u>Cross-References to Related Applications</u>: See 37 CFR 1.78 and MPEP § 201.11.
- (c) <u>Statement Regarding Federally Sponsored Research and Development:</u> See MPEP § 310.
- (d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).
- (e) Incorporation-By-Reference Of Material Submitted On a Compact Disc:
  The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.
- (f) <u>Background of the Invention</u>: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

"Technical Field."

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(1) <u>Field of the Invention</u>: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled

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- (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
- (h) <u>Brief Description of the Several Views of the Drawing(s)</u>: See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (j) <u>Claim or Claims</u>: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR

1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

- (k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).
- (I) <u>Sequence Listing.</u> See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "inner recess" in claims 8 and 9, and "the recess" in claim 10 lack proper antecedent basis in the specification.

#### Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 5, 7, 12, 14, and 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 19-23 of copending Application No. 10/982991 in view of Jaeger (WO 97/12687). Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitations of the claims of the instant applications can be found in the claims of '991.

This is a provisional obviousness-type double patenting rejection.

The limitations of claim 1 of the instant invention can be found in claim 1 of '991. The examiner has interpreted that two nozzle apertures are the inlet side and outlet side.

The difference between claim 1 of the instant application and claim 1 of '991 lies in the fact that the '991's claim includes many more elements and is thus much more specific. Thus the invention of claim 1 is in effect a species of the generic invention of claim 1. Therefore the generic invention is anticipated by the species. See in re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 1 is "anticipated" by claim 1 of the '991, it is not patentably distinct from claim 1.

The limitations of claim 4 of the instant invention can be found in claim 19 of '991. The limitations of claim 5 of the instant invention can be found in claim 20 of '991.

The limitations of claim 7 of the instant invention can be found in claim 1 of '991. The difference between claim 7 of the instant application and claim 1 of '991 lies in the fact that the '991's claim includes many more elements and is thus much more specific. Thus the invention of claim 1 is in effect a species of the generic invention of claim 7. Therefore the generic invention is anticipated by the species. See in re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 7 is "anticipated" by claim 1 of the '991, it is not patentably distinct from claim 1.

In addition, claim 7 adds the features of "at least one of the following surfaces is produced by microtechnology or nanotechnology: - the outer surface of the fluid outlet side of the nozzle, the outer surface of the end face of the nozzle holder, the side wall of the bore or hole of the nozzle holder, the outer surface of the end face of the check nut, or the side wall of the bore or hole of the check nut."

Claim 1 of '991 does not contain these features.

However Jaeger teaches a nozzle system (54) for a device for delivering fluids (First Figure), comprising a nozzle (54) and a nozzle holder (53). "At the nozzle outlet end is at least one circular or non-circular opening less than or equal to 10 micrometers in size" (page 9, last paragraph – page 10, end of paragraph). Therefore the size of the opening as it is measured using the micrometer unit of length, has to have the capability of being formed by microtechnology.

Therefore it would have been obvious to one or ordinary skill in the art at the time of the invention to modify claim 1 of '991 to include a nozzle outlet being produced by microtechnology.

The limitations of claim 12 of the instant invention can be found in claim 21 of '991.

The limitations of claim 14 of the instant invention can be found in claim 23 of '991.

The limitation of claim 15 of the instant invention can be found in claim 22 and also in claim 24 of '991.

#### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The examiner cannot ascertain as to the meaning of "recess" in claims 8 and 9, "recess remote" in claim 10, and "corresponding surface" in claim 18 as the specification of applicant does not contain information on this limitation.

Claim 18 recites the limitation "the corresponding surface." There is insufficient antecedent basis for this limitation in the claim.

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

\*

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Jaeger et al (WO 97/12687). With regard to claims 1 and 12, Jaeger discloses a nozzle (54) for a delivery device for fluids comprising an inlet side and an outlet side wherein the outer surface of the outlet side is produced by microtechnology or nanotechnology. "The nozzle member consists, for example, of two plates of glass and/or silicon firmly joined together, of which at least one plate has one or more microstructured channels which connect the nozzle inlet end to the nozzle outlet end. At the nozzle outlet end is at least one circular or non-circular opening less than or equal to 10 micrometers in size" (page 9, last paragraph – page 10, end of paragraph).

With regard to claim 2, Jaeger discloses the nozzle (54) according to claim 1 comprising at least one nozzle opening. The inlet end of the nozzle is a nozzle opening.

With regard to claim 3, Jaeger discloses the nozzle (54) according to claim 1 comprising at least two nozzle openings oriented so that the jets of fluid emerging from them intersect. "In a nozzle member having at least two nozzle openings at the outlet end, the directions of spray may be inclined relative to one another at an angle from 20 to 160 degrees, preferably at an angle from 60 to 150 degrees. The directions of spraying meet in the vicinity of the nozzle openings" (page 10, first full paragraph). This implies that the jets of fluid would intersect.

With regard to claim 4, Jaeger discloses the nozzle according to claim 1 wherein the nozzle is formed from at least two constructional units. "The nozzle member consists, for example, of two plates of glass and/or silicon firmly joined together" (page

9, fourth paragraph). Each plate of glass being a constructional unit makes for two total constructional units.

With regard to claim 5, Jaeger discloses the nozzle (54) according to claim 4 wherein the constructional units comprise superimposed plates so that the plates lying one on top of the other define, on one side, a fluid inlet connected to a channel system and/or a filter system which then opens into one or more fluid outlets.

"The nozzle member consists, for example, of two plates of glass and/or silicon firmly joined together, of which at least one plate has one or more microstructured channels which connect the nozzle inlet end to the nozzle outlet end" (page 9, fourth paragraph-end).

Since the two plates are joined together, they can be said to be superimposed and can be said to be lying one on top of the other. Also, the fluid inlet is connected to the fluid outlet by a microstructured channel, which, when considering the broadness, can be said to be a channel system.

This is a product-by-process claim where the product is the superimposed plates lying one on top of the other define, on one side, a fluid inlet connected to a channel system and/or a filter system which then opens into one or more fluid outlets. The process or method of production is microtechnology.

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

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unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 227 USPQ 964, 966 (Fed. Cir. 1985) (Citations omitted).

With regard to claim 6, Jaeger discloses the nozzle (54) according to claim 5 wherein the nozzle has at least two nozzle outlets oriented towards one another. "In a nozzle member having at least two nozzle openings at the outlet end, the directions of spray may be inclined relative to one another at an angle from 20 to 160 degrees, preferably at an angle from 60 to 150 degrees" (page 10, first full paragraph). The orientation of the outlets meets the limitation that the nozzle outlets are oriented towards each other.

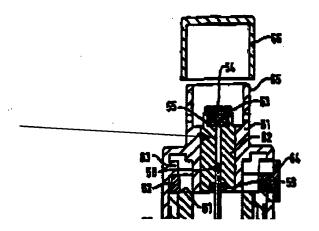
With regard to claim 7, Jaeger discloses a nozzle system (54) for a device for delivering fluids (First Figure), comprising a nozzle (54) and a nozzle holder (53).

Jaeger discloses that "at the nozzle outlet end is at least one circular or non-circular opening less than or equal to 10 micrometers in size (page 9, last paragraph – page 10, end of paragraph). Therefore the size of the opening as it is measured using the micrometer unit of length, has to have the capability of being formed by microtechnology. The examiner has interpreted the claim language that the applicant has used to mean that either a nozzle, or a nozzle and check nut, or a check nut is claimed. Therefore, the examiner selected the first of the three choices to determine the merits of the claim: the nozzle.

With regard to claim 8, Jaeger discloses the nozzle system according to claim 7 wherein the nozzle holder (54) comprises a bore (7) or hole (7), which is constructed as an inner recess which widens out (33) continuously from the nozzle opening.

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With regard to claim 10, Jaeger discloses a side of a recess remote from the nozzle opening



the arrow points to the side of the recess, remote to the nozzle opening (54).

Jaeger does not disclose however that this structure is produced by microtechnology or nanotechnology. However, this is a product-by-process claim where the product is side of the recess, remote to the nozzle opening and the process is producing this said structure by microtechnology or nanotechnology.

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 227 USPQ 964, 966 (Fed. Cir. 1985) (Citations omitted).

With regard to claim 11, Jaeger discloses the nozzle system according to claim 7 wherein the nozzle comprises an outlet side and an inlet side. "The nozzle member consists, for example, of two plates of glass and/or silicon firmly joined together, of

which at least one plate has one or more microstructured channels which connect the nozzle inlet end to the nozzle outlet end. At the nozzle outlet end is at least one circular or non-circular opening less than or equal to 10 micrometers in size" (page 9, last paragraph – page 10, end of paragraph).

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With regard to claim 12, Jaeger discloses a nozzle (54) for a delivery device for fluids (front figure, on first page) comprising an inlet side and an outlet side wherein the outer surface of the outlet side is produced by microtechnology or nanotechnology. "The nozzle member consists, for example, of two plates of glass and/or silicon firmly joined together, of which at least one plate has one or more microstructured channels which connect the nozzle inlet end to the nozzle outlet end. At the nozzle outlet end is at least one circular or non-circular opening less than or equal to 10 micrometers in size" (page 9, last paragraph, - page 10, end of paragraph). Production of the claimed structure by microtechnology is a product-by-process limitation. "Even though productby-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695. 227 USPQ 964, 966 (Fed. Cir. 1985) (Citations omitted).

With regard to claim 13, Jaeger discloses a nozzle system (54) for a device for delivering fluids (front figure) comprising a nozzle (54) and a nozzle holder (53). Jaeger discloses that "at the nozzle outlet end is at least one circular or non-circular opening"

less than or equal to 10 micrometers in size (page 9, last paragraph – page 10, end of paragraph). Production of the claimed structure by microtechnology is a product-by-process limitation. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 227 USPQ 964, 966 (Fed. Cir. 1985) (Citations omitted).

With regard to claim 14, Jaeger discloses a delivery device according to claim 13 comprising a lower (70) and an upper housing part (51) mounted to be rotatable relative to one another (as is made indicative by the two parts being separated by a space) the upper part of the housing (51) containing a spring housing (67) with a spring (68) which is tensioned by rotating the two housing parts. "The spring housing (67) with compression spring (68) is rotatably mounted on the upper housing part by means of the snapping lug (69) and rotary bearing. The lower housing part (70) is pushed over the spring housing and rotates with it to operate the helical sawtooth cam drive (not shown) for cocking the atomiser (moving it from the Fig 6b position to the Fig 6a condition)" (Page 21, First Full Paragraph). Further, by means of a locking clamping mechanism (62) and is released by pressing a release button (64) on the upper part of the housing (51), the spring moving a power take-off flange (56) connected to a piston

(57) on the lower end (70) of which a container (71) can be fitted, and at the upper end (51) of which are found a valve (58) and a pressure chamber (4) which is connected from fluid transmission to the nozzle or the nozzle system formed in the upwardly open part of the upper housing part. "In order to take in the fluid, the hollow piston is lifted partly out of the cylinder, whereupon the valve automatically opens. The fluid flows through the bore (7) in the hollow piston and past the valve member into the high pressure chamber (4)" (Page 17, Paragraph 4).

With regard to claim 15, Jaeger discloses the delivery device for pharmaceutical fluids according to claim 12 wherein the device is an inhaler or atomiser ["the atomiser is preferably a metered dose inhaler" (Page 3, Paragraph One)] for delivering medicinal or pharmaceutical fluids ["the invention relates to a device for producing high pressure in a fluid" and "the invention further relates to a high pressure atomiser which contains this device, and the use thereof, preferably for medicinal purposes" (Page 3, Paragraph One)].

#### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaeger et al (WO 97/12687) in view of Waldrum (5,823,436).

Jaeger substantially discloses the invention as claimed, see rejection to claim 1 and 12 above; however, Jaeger does not expressly disclose surface structure elevations and/or depressions with a height/depth of 0.1 to 100 microns at least on one of the following surfaces: the outer surface of the liquid outlet side of the nozzle, the outer surface of the end face of the nozzle holder, the side wall of the bore or hole of the nozzle holder, the outer surface of the end face of the check nut, or the side wall of the bore or hole of the check nut. The examiner selected the outer surface of the liquid outlet side of the nozzle, which Jaeger has disclosed.

However, Waldrum teaches that the spacing (i.e. height) between the elevations and depressions are in the range of from 0.1 to 200 microns (Abstract). "For example, the downward jets can be emitted through grooves of 0.005 inch, the upward jets through grooves of 0.015 inch, and the central jets through grooves of 0.010 inch" (column 7, lines 1-4). As seen in Figure 2, the grooves 36 are located on top of outlet orifice 34 of the nozzle body 22, so that would be the outer surface of the liquid outlet side of the nozzle. Waldrum further teaches that "in order to improve the evenness of application, it is possible to vary either or both of the density and the size of the grooves in order to reduce this effect" (column 6, lines 61-63). In addition "grooves 36 form a

line 72 of orifices 34 for emission of the fluid in a fan shaped spray pattern 74" (column 5, lines 3-5).

Therefore, it would have been obvious, to one of ordinary skill in the art at the time of the invention, to modify the outer surface of the liquid outlet side of the nozzle of Jaeger so that it includes grooves, or elevations and/or depressions on the surface structure as taught by Waldrum in order to emit uniform droplet sizes from 0.1 to 100 microns in size because doing so would provide an evenness of the application of the spray as taught by Waldrum.

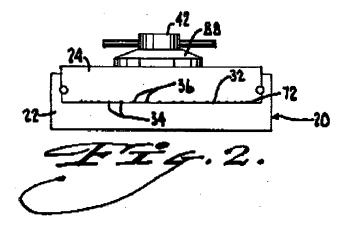
With respect to claim 17, Waldrum teaches wherein the spacings between the elevations and depressions are in the range from 0.1 to 200 microns. "One or both of the nozzle plug and the nozzle body have a plurality of narrow grooves (or elevations and/or depressions on the surface structure). This dimension of 0.001 to 0.015 inch is uquivalent to 25 to 400 microns in width and therefore covers the claimed range (Abstract).

With respect to claim 18, the production by microtechnology/nanotechnology is a product-by-process limitation. As shown in Figure 2, the grooves (36) of Waldrum appear to account for at least 20%, more than likely much more, of the corresponding surface.

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

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unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 227 USPQ 964, 966 (Fed. Cir. 1985) (Citations omitted).



With respect to claim 19, Jaeger/Waldrum teach elevations/depressions as shown in the rejection of claims 16 and 17. This is a product by process claim where the product is the elevations/depressions and the process is producing the said elevations/depressions by hydrophobic materials, glass and/or ceramics and/or metals and/or plastics selected from polyethylene, polypropylene, polycarbonate, polyacrylate, polyester and silanes.

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 227 USPQ 964, 966 (Fed. Cir. 1985) (Citations omitted).

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With respect to claim 20, Jaeger/Waldrum teach elevations/depressions as shown in the rejection of claims 16 and 17. This is a product by process claim where the product is the elevations/depressions and the process is producing the said elevations/depressions by subtractive or additive treatment of the surfaces, the treatment selected from stamping, etching, laser ablation, galvanic machining, adhesively attaching a structured film, adhesion of a powder, spraying with suspensions and depositing sublimates.

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 227 USPQ 964, 966 (Fed. Cir. 1985) (Citations omitted).

#### Allowable Subject Matter

Claim 9 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

#### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show nozzle systems for delivery of fluids.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jasveer Singh whose telephone number is (571) 272-5508. The examiner can normally be reached on M-F (9am - 6pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Jasveer Singh Patent Examiner Art Unit 3772

November 8, 2006

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